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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,730	01/02/2002	Robert M. Abrams	269/106 (cont.)	3733

7590 03/10/2004

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,730

Applicant(s)

ABRAMS ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 32-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicants response filed 11-18-03 has been received and entered.
1. Applicant's election of the invention of group IV in the paper filed 11-18-03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. In view of applicants and for clarity of prosecution, the restriction requirement has been modified as follows. In their response to this new restriction, applicants are required to reiterate their election in case some requirements may be the same as in the previous office action.
3. Claims 32-60 are pending.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 32-37, 40, 41, 43, 44, 46, 53-60, drawn to a precursor composition comprising polymer forming biodegradable material and a biologically active component wherein the biologically active component is a protein or peptide, classified in class 514, subclass 2.
  - II. Claims 32-37, 40, 41, 42, 44, 45, 47-60, drawn to a precursor composition comprising polymer forming biodegradable material and a biologically active component wherein the biologically active component is nucleic acid or gene/vector systems, classified in class 514, subclass 44.
  - III. Claims 32-37, 40, 41, 53-60, drawn to a precursor composition comprising polymer forming biodegradable material and a biologically active component wherein the biologically active component is an antisense gene or oligonucleotide, classified in class 514, subclass 44.

- IV. Claims 32-37, 40, 41, 53-60, drawn to a precursor composition comprising polymer forming biodegradable material and a biologically active component wherein the biologically active component is a phospholipid, classified in class 514, subclass 1.77.
- V. Claims 32-37, 40, 41, 53-60, drawn to a precursor composition comprising polymer forming biodegradable material and a biologically active component wherein the biologically active component is a polymers with phosphorylcholine functionality, classified in class 514, subclass 462.
- VI. Claims 32-37, 40, 41, 44, 53-60, drawn to a precursor composition comprising polymer forming biodegradable material and a biologically active component wherein the biologically active component is a compound, classified in class 514, subclass 1.
- VII. Claims 32-37, 40, 41, 44, 53-60, drawn to a precursor composition comprising polymer forming biodegradable material and a biologically active component wherein the biologically active component is a DSN compacting agent, classified in class 514, subclass 1.
- VIII. Claims 32-37, 40, 41, 44, 53-60, drawn to a precursor composition comprising polymer forming biodegradable material and a biologically active component wherein the biologically active component is a virus, classified in class 424, subclass 93.1.
- IX. Claims 32-37, 40, 41, 44, 53-60, drawn to a precursor composition comprising polymer forming biodegradable material and a biologically active component wherein the biologically active component is a liposome, classified in class 424, subclass 450.

4. Claims 32 link inventions of the groups I-IX. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claims 32. Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s)

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depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 USC 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129,131-132 (CCPA 1971). See also MPEP 804.01.

5. Inventions of the groups I-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions are drawn to compositions that have different structure, function and utility and search one compound in the patent or non-patent literature will not be coextensive. Additionally, they have been classified in different class and subclass. It is noted that while these compositions have been listed as a Markush group, the compositions are not species of a genus since they have different structure, function and utility and do not have any characteristics in common.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

polyglycolic acid, polylactic acid, polycaprolactone and their copolymers in claim 35;

polyhydroxybutyrate, polyhydroxyvalerate and their copolymers in claim 36;  
firbronectin, laminin, bitronectin, hyaluronic acid, silko-elastin, elastin, fibrinogen, and other basement membrane proteins in claim 43.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species in each claim for prosecution on the merits to which the claims shall be restricted if

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no generic claim is finally held to be allowable. Currently, claims 35, 36 and 43 are generic for the species listed.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

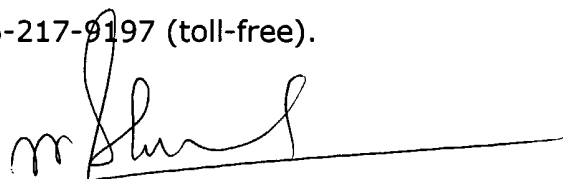
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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (571) 272-0548.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632



**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**